

Sheet 1 of 6

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|--|---------------|---|--------------------------|---------------------------------|-------------------------------|--------------------------|----------------------------|
| U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE<br><br>INFORMATION DISCLOSURE STATEMENT   |               |   |                          | ATTY. DOCKET NO.<br>3220-100466 |                               | SERIAL NO.<br>10/550,427 |                            |
|  |               |   |                          | APPLICANT<br>Webster et al.     |                               |                          |                            |
|  |               |   |                          | FILING DATE<br>October 5, 2006  |                               | GROUP<br>3738            |                            |
| U.S. PATENT DOCUMENTS  |               |   |                          |                                 |                               |                          |                            |
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|  | AA            | 6,929,539   | Aug. 16, 2005            | Schutz et al.                   |                               |                          |                            |
|  | AB            | 6,881,249   | April 19, 2005           | Anderson et al.                 |                               |                          |                            |
|  | AC            | 6,797,514   | Sept. 28, 2004           | Berenson et al.                 |                               |                          |                            |
|  | AD            | 6,790,455   | Sept. 14, 2004           | Chu et al.                      |                               |                          |                            |
|  | AE            | 6,756,286   | June 29, 2004            | Moriceau et al.                 |                               |                          |                            |
|  | AF            | 6,689,374   | Feb. 10, 2004            | Chu et al.                      |                               |                          |                            |
|  | AG            | 6,669,706   | Dec. 30, 2003            | Schmitt et al.                  |                               |                          |                            |
|  | AH            | 6,572,672   | June 3, 2003             | Yadav et al.                    |                               |                          |                            |
|  | AI            | 6,396,208   | May 28, 2002             | Oda et al.                      |                               |                          |                            |
|  | AJ            | 6,368,859   | Apr. 9, 2002             | Atala                           |                               |                          |                            |
|  | AK            | 6,355,198   | Mar. 12, 2002            | Kim et al.                      |                               |                          |                            |
| FOREIGN PATENT DOCUMENTS   |               |   |                          |                                 |                               |                          |                            |
|  |               | Document Number   | Date                     | Country                         | Class                         | Subclass                 | Translation Yes No         |
|  | <del>AL</del> | <del>WO 07/25000</del>  | <del>July 24, 1997</del> | <del>WO</del>                   |                               |                          |                            |
|  | AM            | WO 01/55473   | Aug. 2, 2001             | WO                              |                               |                          |                            |
|  | AN            | WO 03/015886  | Feb. 27, 2003            | WO                              |                               |                          | no copies                  |
|  | AO            |   |                          |                                 |                               |                          |                            |
|  | AP            |   |                          |                                 |                               |                          |                            |
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|  | AR            | J. Black and G. Hastings, "Handbook of Biomaterial Properties", <i>Chapman &amp; Hall</i> , pgs. 40-47 (1998)   |                          |                                 |                               |                          |                            |
|  | AS            | Mankin et al., "Orthopaedic Basic Science - Chapter 1 Form and Function of Articular Cartilage", <i>American Academy of Orthopaedic Surgeons</i> , pgs. 1-45, (1994)  |                          |                                 |                               |                          |                            |
|  | AT            | Kay et al., "Nanostructured Polymer/Nanophase Ceramic Composites Enhance Osteoblast and Chondrocyte Adhesion", <i>Tissue Engineering</i> , Vol. 8, No. 5, pgs 753-761, (2002)   |                          |                                 |                               |                          |                            |
|  | AU            | Thapa et al., "An Investigation of Nano-structured Polymers for Use as Bladder Tissue Replacement Constructs", <i>Mat. Res. Soc. Symp. Proc.</i> , Vol. 711, pgs 205-210, (2002)  |                          |                                 |                               |                          |                            |
|  | AV            | Miller et al., "An <i>In Vitro</i> Study of Nano-fiber Polymers for Guided Vascular Regeneration", <i>Mat. Res. Soc. Symp. Proc.</i> , Vol. 711, pgs. 201-204, (2002)   |                          |                                 |                               |                          |                            |
|  | AW            | Jun et al., "An <i>In Vitro</i> Study of Chondrocyte Function on Nanostructured Polymer/Ceramic Formulations to Improve Cartilage Repair", <i>Nano 2002 Conference Abstract Book</i> , Orlando, FL, pg 269, (2002)  |                          |                                 |                               |                          |                            |
|  | AX            | Tepper et al., "Nanosized alumina fibers," <i>American Ceramic Society Bulletin</i> , 80(6):57-60 (2001).   |                          |                                 |                               |                          |                            |
|  | AY            | Webster et al., "An <i>in vitro</i> evaluation of nanophase alumina for orthopaedic/dental applications," <i>BioCeramics Volume 11 (Proceedings of the 11th International Symposium on Ceramics in Medicine)</i> , 273-76 (LeGeros & LeGeros eds., World Scientific Publishing Co, 1998). |                          |                                 |                               |                          |                            |
|  | <del>AZ</del> | <del>Webster et al., "Hydroxylapatite with substituted magnesium, zinc, cadmium, and yttrium. II. Mechanisms of osteoblast adhesion," <i>J. Biomed. Mater. Res.</i>, 59:312-17 (2002).</del>  |                          |                                 |                               |                          |                            |
| Examiner<br>/Bruce Snow/   |               |   |                          |                                 | Date Considered<br>03/24/2010 |                          |                            |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.<br>Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |               |   |                          |                                 |                               |                          |                            |

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| U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE<br><br>INFORMATION DISCLOSURE STATEMENT   |    |  |                | ATTY. DOCKET NO.<br>3220-100466 |                 | SERIAL NO.<br>10/550,427 |                            |
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| U.S. PATENT DOCUMENTS  |    |  |                |                                 |                 |                          |                            |
| *Examiner Initial  |    | Document Number  | Date           | Name                            | Class           | Subclass                 | Filing Date if Appropriate |
|  | BA | 6,344,367  | Fe. 5, 2002    | Naya et al.                     |                 |                          |                            |
|  | BB | 6,319,264  | Nov. 20, 2001  | Tormala et al.                  |                 |                          |                            |
|  | BC | 6,291,070  | Sept. 18, 2001 | Arpac et al.                    |                 |                          |                            |
|  | BD | 6,262,017  | July 17, 2001  | Dee et al.                      |                 |                          |                            |
|  | BE | 6,183,255  | Feb. 6, 2001   | Oshida                          |                 |                          |                            |
|  | BF | 6,106,913  | Aug. 22, 2000  | Scardino et al.                 |                 |                          |                            |
|  | BG | 5,733,337  | Mar. 31, 1998  | Carr Jr. et al.                 |                 |                          |                            |
|  | BH | 5,415,704  | May 16, 1995   | Davidson                        |                 |                          |                            |
|  | BI | 5,306,311  | April 26, 1994 | Stone et al.                    |                 |                          |                            |
|  | BJ | 5,292,328  | Mar. 8, 1994   | Hain et al.                     |                 |                          |                            |
|  | BK | 4,998,239  | Mar. 5, 1911   | Strandjord et al.               |                 |                          |                            |
| FOREIGN PATENT DOCUMENTS   |    |  |                |                                 |                 |                          |                            |
|  |    | Document Number  | Date           | Country                         | Class           | Subclass                 | Translation<br>Yes No      |
|  | BL |  |                |                                 |                 |                          |                            |
|  | BM |  |                |                                 |                 |                          |                            |
|  | BN |  |                |                                 |                 |                          |                            |
|  | BO |  |                |                                 |                 |                          |                            |
|  | BP |  |                |                                 |                 |                          |                            |
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|  | BR | Dee et al., "Design and function of novel osteoblast-adhesive peptides for chemical modification of biomaterials," <i>J. Biomed. Mater. Res.</i> , 40:371-77 (1998).   |                |                                 |                 |                          |                            |
|  | BS | Webster et al., "Specific proteins mediate enhanced osteoblast adhesion on nanophase ceramics," <i>J. Biomed. Mater. Res.</i> , 51:475-83 (2000).  |                |                                 |                 |                          |                            |
|  | BT | Webster et al., "Enhanced functions of osteoblasts on nanophase ceramics," <i>Biomaterials</i> , 21:1803-10 (2000).  |                |                                 |                 |                          |                            |
|  | BU | Curtis & Wilkinson, "Review. Topographical control of cells," <i>Biomaterials</i> , 18(24):1573-83 (1997).   |                |                                 |                 |                          |                            |
|  | BV | Puleo & Bizios, "RGDS tetrapeptide binds to osteoblasts and inhibits fibronectin-mediated adhesion," <i>Bone</i> , 12:271-76 (1991).   |                |                                 |                 |                          |                            |
|  | BW | Siegel, "Creating nanophase materials," <i>Scientific American</i> , 275(6):74 (1996).   |                |                                 |                 |                          |                            |
|  | BX | Webster et al., "Design and evaluation of nanophase alumina for orthopaedic/dental applications," <i>Nanostructured Materials</i> , 12:983-86 (1999).  |                |                                 |                 |                          |                            |
|  | BY | Webster et al., "Enhanced surface and mechanical properties of nanophase ceramics to achieve orthopaedic/dental implant efficacy," <i>Key Engineering Materials</i> , Vols. 192-195, pp 321-24 (Proceedings of the 13th international symposium on ceramics in medicine, Bologna, Italy, 2000 (Trans Tech Publications, 2001). |                |                                 |                 |                          |                            |
|  | BZ | Webster et al., "Mechanisms of enhanced osteoblast adhesion on nanophase alumina involve vitronectin," <i>Tissue Engineering</i> , 7(3):291-301 (2001).  |                |                                 |                 |                          |                            |
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|  |    |  |               | APPLICANT<br>Webster et al.     |                 |                          |                            |
|  |    |  |               | FILING DATE<br>October 5, 2006  |                 | GROUP<br>3738            |                            |
| U.S. PATENT DOCUMENTS  |    |  |               |                                 |                 |                          |                            |
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|  | CA | 4,795,436  | Jan. 3, 1989  | Robinson                        |                 |                          |                            |
|  | CB | 2006/0173471   | Aug. 3, 2006  | Carr Jr. et al.                 |                 |                          |                            |
|  | CC | 2004/0241211   | Dec. 2, 2004  | Fischell et al.                 |                 |                          |                            |
|  | CD | 2004/0171323   | Sept. 2, 2004 | Shalaby                         |                 |                          |                            |
|  | CE | 2004/0131753   | July 8, 2004  | Smith et al.                    |                 |                          |                            |
|  | CF | 2004/0104672   | June 3, 2004  | Shiang et al.                   |                 |                          |                            |
|  | CG | 2004/0028875   | Feb. 12, 2004 | Van Rijn et al.                 |                 |                          |                            |
|  | CH | 2003/0050711   | Mar. 13, 2003 | Laurencin et al.                |                 |                          |                            |
|  | CI | 2003/0040809   | Feb. 27, 2003 | Goldmann et al.                 |                 |                          |                            |
|  | CJ | 2002/0173213   | Nov. 21, 2002 | Chu et al.                      |                 |                          |                            |
|  | CK | 2002/0173033   | Nov. 21, 2002 | Hammerick et al.                |                 |                          |                            |
| FOREIGN PATENT DOCUMENTS   |    |  |               |                                 |                 |                          |                            |
|  |    | Document Number  | Date          | Country                         | Class           | Subclass                 | Translation<br>Yes No      |
|  | CL |  |               |                                 |                 |                          |                            |
|  | CM |  |               |                                 |                 |                          |                            |
|  | CN |  |               |                                 |                 |                          |                            |
|  | CO |  |               |                                 |                 |                          |                            |
|  | CP |  |               |                                 |                 |                          |                            |
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|  | CR | Webster et al., "Nanoceramic surface roughness enhances osteoblast and osteoclast functions for improved orthopaedic/dental implant efficacy," <i>Scripta Mater.</i> , 44:1639-42 (2001).  |               |                                 |                 |                          |                            |
|  | CS | Jean-Louis Pariente et al., "In vitro biocompatibility assessment of naturally derive and synthetic biomaterials using normal human urothelial cells," <i>J. Biomed. Mater. Res.</i> , 55(1), (2001), pgs. 33-39   |               |                                 |                 |                          |                            |
|  | CT | Malachy J. Gleeson et al., "The use of alloplastic biomaterials in bladder substitution," <i>J. Urol.</i> , 148, (1992), pgs. 1377-1382  |               |                                 |                 |                          |                            |
|  | CU | Janeta Nikolovski et al., "Smooth muscle cell adhesion to tissue engineering scaffolds," <i>Biomater.</i> , 21, (2000), pgs. 2025-2032   |               |                                 |                 |                          |                            |
|  | CV | Anthony Atala et al., "Implantation <i>in vivo</i> and retrieval of artificial structures consisting of rabbit and human urothelium and human bladder muscle," <i>J. Urol.</i> , 150, (1993), pgs. 608-612   |               |                                 |                 |                          |                            |
|  | CW | M. J. Lyndon et al., "Cellular interactions with synthetic polymer surfaces in culture," <i>Biomater.</i> 6, (1985), pgs. 396-402  |               |                                 |                 |                          |                            |
|  | CX | A. S. G. Curtis et al., "Adhesion of cells to polystyrene surfaces," <i>J. Cell Biol.</i> , 97, (1983), pgs. 1500-1506   |               |                                 |                 |                          |                            |
|  | CY | Joseph A. Chinn et al., "Enhancement of serum fibronectin adsorption and the clonal plating efficiencies of Swiss mouse 3T3 fibroblast and MM14 mouse myoblast cells on polymer substrates modified by radiofrequency plasma deposition," <i>J. Colloid Interface Sci.</i> , 127, (1989), pgs. 67-87 |               |                                 |                 |                          |                            |
|  | CZ | Paul Goldhaber, "The influence of pore size on carcinogenicity of subcutaneously implanted Millipore filters," <i>Proc. Am. Assoc. Cancer Res.</i> , 3 (1961), pg. 28  |               |                                 |                 |                          |                            |
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| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.<br>Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |  |               |                                 |                 |                          |                            |

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|  |    |  |               | APPLICANT<br>Webster et al.     |                 |                          |                            |
|  |    |  |               | FILING DATE<br>October 5, 2006  |                 | GROUP<br>3738            |                            |
| U.S. PATENT DOCUMENTS  |    |  |               |                                 |                 |                          |                            |
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|  | DA | 2002/0167118   | Nov. 14, 2002 | Billiet et al.                  |                 |                          |                            |
|  | DB | 6,805,898  | Oct. 19, 2004 | Wu et al.                       |                 |                          |                            |
|  | DC | 4,776,853  | Oct. 11, 1988 | Klement et al.                  |                 |                          |                            |
|  | DD | 4,902,508  | Feb. 20, 1990 | Badylak et al.                  |                 |                          |                            |
|  | DE | 5,281,422  | Jan. 25, 1994 | Badylak et al.                  |                 |                          |                            |
|  | DF | 5,372,821  | Dec. 13, 1994 | Badylak et al.                  |                 |                          |                            |
|  | DG | 5,573,784  | Nov. 12, 1996 | Badylak et al.                  |                 |                          |                            |
|  | DH | 5,744,515  | Apr. 28, 1998 | Clapper                         |                 |                          |                            |
|  | DI | 6,270,347  | Aug. 7, 2001  | Webster et al.                  |                 |                          |                            |
|  | DJ |  |               |                                 |                 |                          |                            |
|  | DK |  |               |                                 |                 |                          |                            |
| FOREIGN PATENT DOCUMENTS   |    |  |               |                                 |                 |                          |                            |
|  |    | Document Number  | Date          | Country                         | Class           | Subclass                 | Translation<br>Yes No      |
|  | DL |  |               |                                 |                 |                          |                            |
|  | DM |  |               |                                 |                 |                          |                            |
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|  | DR | J. Brauker et al., "Neovascularization of immunoisolation membranes: the effect of membrane architecture and encapsulated tissue," <i>Transplant Proc.</i> , 24, (1992); pg. 2924            |               |                                 |                 |                          |                            |
|  | DS | Paul Weiss, "In vitro experiments on the factors determining the course of the outgoing nerve fiber," <i>J. Exp. Zool.</i> , 68, (1945), pgs. 393-448  |               |                                 |                 |                          |                            |
|  | DT | G. A. Dunn et al., "Alignment of fibroblasts on grooved surfaces described by a simple geometric transformation," <i>J. Cell Sci.</i> , 83, (1986), pgs. 313-340                             |               |                                 |                 |                          |                            |
|  | DU | J. Meyle et al., "Variation in contact guidance by human cells on a microstructured surface," <i>J. Biomed. Mater. Res.</i> , 29, (1995), pgs. 81-88   |               |                                 |                 |                          |                            |
|  | DV | John A. Schmidt et al., "Macrophage response to microtextured silicone," <i>Biomater.</i> , 12, (1992), pgs. 385-389   |               |                                 |                 |                          |                            |
|  | DW | Karen M. Haberstroh et al., "The effects of sustained hydrostatic pressure on select bladder smooth muscle cell functions," <i>J. Urol.</i> , 162, (1999), pgs. 2114-2118                    |               |                                 |                 |                          |                            |
|  | DX | Jinming Gao et al., "Surface hydrolysis of poly(glycolic acid) meshes increases the seeding density of vascular smooth muscle cells," <i>J. Biomed. Mat. Res.</i> , 42, (1998), pgs. 417-424 |               |                                 |                 |                          |                            |
|  | DY | Mark A. Schubert et al., "Role of oxygen in biodegradation of poly(etherurethane urea) elastomers," <i>J. Biomed. Mat. Res.</i> , 34, (1997), pgs. 519-530                                   |               |                                 |                 |                          |                            |
|  | DZ | Thomas J. Webster et al., "Osteoblast adhesion on nanophase ceramics," <i>Biomaterials</i> , 20, (1999), pgs. 1221-1227  |               |                                 |                 |                          |                            |
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|                          | EP |                 |      |         |       |          |                       |

  

| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) |    |   |
|---|----|---|
|   | ER | M. Conley et al., "Effects of biodegradable polymer particles on rat marrow-derived stromal osteoblasts <i>in vitro</i> ," <i>Biomaterials</i> , 19, (1998), pgs. 1255-1268   |
|   | ES | Susan L. Ishaug-Riley et al., "Three-dimensional culture of rat calvarial osteoblasts in porous biodegradable polymers," <i>Biomaterials</i> 19, (1998), pgs. 1405-1412   |
|   | ET | Susan L. Ishaug-Riley et al., "Human articular chondrocyte adhesion and proliferation on synthetic biodegradable polymer films," <i>Biomaterials</i> , 20, (1999), pgs. 2245-2256   |
|   | EU | Laurence S. Baskin et al., "Cellular Signaling in the Bladder," <a href="http://www.bioscience.org">www.bioscience.org</a> , <i>Frontiers in Bioscience</i> , 2, d592-595, (1997), 8 pgs.   |
|   | EV | Gunilla Dahlfors et al., "Vascular Endothelial Growth Factor and Transforming Growth Factor- $\beta$ 1 Regulate the Expression of Insulin-Like Growth Factor-Binding Protein-3, -4, and -5 in Large Vessel Endothelial Cells," <i>The Endocrinology Society</i> , Vol. 141, No. 6, (2000), pgs. 2062-2067 |
|   | EW | Jinming Gao et al., "Surface hydrolysis of poly(glycolic acid) meshes increases the seeding density of vascular smooth muscle cells," <i>J. Biomed Mater Res</i> , 42, (1998), pgs. 417-424   |
|   | EX | Karen M. Haberstroh et al., "The Effects of Sustained Hydrostatic Pressure on Select Bladder Smooth Muscle Cell Functions," <i>The Journal of Urology</i> , Vol. 162, (1999), pgs. 2114-2118  |
|   | EY | Antonios G. Mikos et al., "Preparation and Characterization of poly(L-lactic acid) foams," <i>Polymer</i> , Vol 35, No. 5, (1994), pgs. 1068-1077   |
|   | EZ | Kenjiro Yamakawa et al., "Peroxisome Proliferator-Activated Receptor- $\gamma$ Agonists Increase Vascular Endothelial Growth Factor Expression in Human Vascular Smooth Muscle Cells," <i>Biochemical and Biophysical Research Communications</i> , 271, (2000), pgs. 571-574                             |

  

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|  |    |   |      |                                 |                               |                          |                            |
|--|----|---|------|---------------------------------|-------------------------------|--------------------------|----------------------------|
| U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE<br><br>INFORMATION DISCLOSURE STATEMENT   |    |   |      | ATTY. DOCKET NO.<br>3220-100466 |                               | SERIAL NO.<br>10/550,427 |                            |
|  |    |   |      | APPLICANT<br>Webster et al.     |                               |                          |                            |
|  |    |   |      | FILING DATE<br>October 5, 2006  |                               | GROUP<br>3738            |                            |
| U.S. PATENT DOCUMENTS  |    |   |      |                                 |                               |                          |                            |
| *Examiner Initial  |    | Document Number   | Date | Name                            | Class                         | Subclass                 | Filing Date if Appropriate |
|  | FA |   |      |                                 |                               |                          |                            |
|  | FB |   |      |                                 |                               |                          |                            |
|  | FC |   |      |                                 |                               |                          |                            |
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|  | FE |   |      |                                 |                               |                          |                            |
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|  | FJ |   |      |                                 |                               |                          |                            |
|  | FK |   |      |                                 |                               |                          |                            |
| FOREIGN PATENT DOCUMENTS   |    |   |      |                                 |                               |                          |                            |
|  |    | Document Number   | Date | Country                         | Class                         | Subclass                 | Translation<br>Yes No      |
|  | FL |   |      |                                 |                               |                          |                            |
|  | FM |   |      |                                 |                               |                          |                            |
|  | FN |   |      |                                 |                               |                          |                            |
|  | FO |   |      |                                 |                               |                          |                            |
|  | FP |   |      |                                 |                               |                          |                            |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |   |      |                                 |                               |                          |                            |
|  | FR | Young-Jo Kim et al., "Fluorometric Assay of DNA in Cartilage Explants Using Hoechst 33258," <i>Analytical Biochemistry</i> , 174, (1988), pgs. 168-176  |      |                                 |                               |                          |                            |
|  | FS | Kari I. Kivirikko et al., "Modifications of a Specific Assay for Hydroxyproline in Urine," <i>Analytical Biochemistry</i> , 19, (1967), pgs. 249-255  |      |                                 |                               |                          |                            |
|  | FT | C. B. Wilson et al., "Extracellular matrix and integrin composition of the normal bladder wall," <i>World J Urol.</i> 14, (1996), pgs. S30-S37  |      |                                 |                               |                          |                            |
|  | FU | Paul Weiss, "Experiments on Cell and Axon Orientation in Vitro: The Role of Colloidal Exudates in Tissue Organization," <i>Journal of Experimental Zoology</i> , vol. 100(3), (1943), pgs 353-386 |      |                                 |                               |                          |                            |
|  | FV |   |      |                                 |                               |                          |                            |
|  | FW |   |      |                                 |                               |                          |                            |
|  | FX |   |      |                                 |                               |                          |                            |
|  | FY |   |      |                                 |                               |                          |                            |
|  | FZ |   |      |                                 |                               |                          |                            |
| Examiner<br>/Bruce Snow/   |    |   |      |                                 | Date Considered<br>02/30/2010 |                          |                            |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.<br>Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |   |      |                                 |                               |                          |                            |

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